HASAN AND SINGH

Intellectuals @ Law

Advocates, Patent And Trademark Attorneys

Newsletter February 2015

1. India's Patent Office refuses patent to Gilead for its drug Sovaldi.

India's patent office has refused a patent to US drugmaker Gilead for its blockbuster drug Sovaldi on the grounds that the molecules and compounds of the drug were "known" elements. Sovaldi is considered one of the most effective treatments for Hepatitis C

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2. Delhi HC stops Cipla's generic drug sales.

The Delhi high court has decided in favour of drug MNC Novartis, restraining generic firm Cipla from selling its affordable version of respiratory drug Onbrez in the domestic market. The court on 9th January issued an interim injunction directing Cipla to stop the sale of the generic drug in the market, and apply for a compulsory licence on the drug if it feels that sufficient quantities are not available for patients in the country.

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3. Patent Office sets aside earlier order granting patent to Abbott's Humira.

The Patent Office has set aside its earlier order granting patent to Abbott Biotechnology Ltd's rheumatoid arthritis drug Humira, one of its key products, in review of a pre-grant opposition filed by Glenmark Pharmaceuticals. The decision comes after the Delhi High Court asked the Patent Office to consider Glenmark's pre-grant opposition as a petition to review the earlier decision of the controller.

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4. Patent Office revokes the patent of Roche's osteoporosis drug Bonviva.

The Patent Office has revoked the patent of Swiss drug major F Hoffmann-La Roche AG for its osteoporosis drug ibandronate sodium - sold under the brand Boniva in the US and Bonviva in Asia - on a post-grant opposition filed by Cipla. The decision was taken after the Intellectual Property Appellate Board (IPAB) referred the issue back to the patent office, setting aside a previous order by the patent office, which refused Cipla's post-grant opposition.

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5. World's first inactivated Sabin polio vaccine approved by China FDA.

China's FDA has awarded marketing approval of the world's first Sabin strain inactivated polio vaccine, marking a milestone as well for the Institute of Medical Biology of the Academy of Medical Sciences.

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6. Gilead to challenge hepatitis C drug patent rejection decision.

Gilead Sciences Inc will appeal against the decision of the Indian Patent Office rejecting its patent application for hepatitis C drug sofosbuvir. This rejection relates to the patent application covering the metabolites of sofosbuvir. Gilead is pleased that the Patent Office found in favour of the novelty and inventiveness of its claims.

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7. Strides Arcolab, Gilead join hands for marketing HIV drugs.

Strides Arcolab Limited has entered into a licensing agreement with Gilead Sciences, Inc for marketing HIV drugs. Under the agreement, Gilead has extended non-exclusive rights to Strides to manufacture and distribute Tenofovir Alafenamide (TAF) - used for treatment of AIDS.The license being granted to Strides extends to 112 countries.

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8. Morocco recognises European patents as national patents.

Morocco is the first non-member country of the European Patent Organisation to validate the legal effects of a European patent on its territory.

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9. Delhi HC asks Glenmark to stop making Linezolid drug.

The Delhi high court on 19th January, 2015 restrained Mumbai-based generic drug maker Glenmark Pharmaceuticals Ltd from manufacturing and selling, directly or indirectly, Linezolid, manufactured through the process patented by the Hyderabad-based pharma company Symed

Laboratories Ltd. Linezolid is a synthetic antibiotic used to treat infections, including pneumonia, and infections of the skin and blood.

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10. US Supreme Court rules for Teva over MS drug patent.

In the high profile patent tussle on multiple sclerosis drug Copaxone, for which Natco has a first to file status, the US Supreme Court has favored Teva. It's a ruling that will delay entry of generics in the market. US supreme court has suggested that Appeals court did not use the right approach in analyzing whether Teva's September 2015 patent is valid or not.

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11. Gilead expands alliance with Indian partners to include investigational drug.

American drugmaker Gilead Sciences Inc has expanded its Hepatitis C generic licensing agreements with Indian partners to include an investigational drug GS-5816.The still-under-evaluation drug is a single tablet regimen that combines the compound (GS-5816) and sofosbuvir for the treatment of all six genotypes of Hepatitis C, Gilead said. It is at present being evaluated in late-stage or Phase III clinical trials.

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12. Industry seeks Health Ministry intervention on ban of diluted nitroglycerine solution to overcome shortage of life saving drugs.

The pharmaceutical industry in the country has sought the intervention of the Union health ministry to grant a stay for at least two years on the ban imposed by the Petroleum and Explosives Safety Organisation (PESO) on the production of Diluted Nitroglycerine Solution, in order to switch over to a modified formulation and hence overcome the shortage of life-saving drugs in the coming future.

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13. India warns drugmakers failure not an option for price data due next week.

India's National Pharmaceutical Pricing Authority has given drugmakers operating in the country until Feb. 3 to supply the mountain of price and sales material necessary for determining the next round of price caps on 102 drugs on its "essential" list..Earlier in January, the Inter-Ministerial Committee on Price Negotiations for Patented Drugs apparently determined that the drugmakers needed to be prodded to produce the requested material on time. The NPPA issued a memorandum Jan. 27 giving makers of any of the 102 drugs 7 days to provide the information.

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14. PUNEET KAUSHIK vs UNION OF INDIA: In a recent judgment the Delhi High Court stated that PCT application requires prior foreign filing license as Indian Patent Office is merely a receiving office.

Read Judgement..

15. USPTO Issues Post-Alice Abstract Idea Examples.

On January 27, the USPTO provided its promised set of examples of patent-eligible and patent-ineligible claims relating to the abstract idea exception to 35 U.S.C. § 101, in light of Alice Corp. v. CLS Bank. These examples are intended to be used in conjunction with the Office's 2014 Interim Guidance on Patent Subject Matter Eligibility.

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16. PMRUs to monitor drug prices.

A Central sector scheme of assistance was announced to set up price monitoring and resource units (PMRUs) in States and Union Territories to effectively track violations of drug prices fixed by National Pharmaceutical Pricing Authority. Under the scheme, each PMRU will function under the direct supervision of the concerned State Drug Controller and will be operating as a partner of NPPA with information gathering mechanism at the regional levels.

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17. Code for pharma marketing.

From January 1, 2015 a Uniform Code of Pharmaceutical Marketing Practices (UCPMP), issued by the Department of Pharmaceuticals, comes into effect in India after several years of deliberations. As per the Code, no gifts, pecuniary advantages or benefits in kind may be supplied or offered to physicians to prescribe drugs by a pharmaceutical company or any of its agents or distributors.

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